K033008

MAY 1 3 2004

Summary of Safety and Effectiveness

Air Safety Ltd.
NFC House, Vickers Industrial Estate
Mellishaw Lane
Morecambe, Lancaster LA3 3EN
England

Non-Confidential Summary of Safety and Effectiveness

7-May-04

Official Contact:	Steve Brown – Quality Manager
Proprietary or Trade Name:	Air Safety HEPA and non-HEPA Filters
Common/Usual Name:	Bacterial / Viral Filters
Classification Name:	Filter, Bacterial, Breathing Circuit, CAH
Predicate Devices:	Engineered Medical Systems – HEPA - K013089 Non-HEPA – K013122 Smiths Filter – K002201 NPB D/X7 - K964540 and K984379

Device Description

The Air Safety HEPA and Non-HEPA filters are available in multiple sizes and shapes, and incorporate standard 15 / 22 mm connectors with or without a gas sampling luer port. Some models adapt to fit ventilator exhalation limb only. The depth (HEPA filtration) filter uses a pleated paper fiber for filtration. Filters are tested for rating performance according to EN 13328 Salt for Breathing System filtration performance. The "HEPA" performance was also tested in accordance to DOE-3025-99, DOE-3020-97 and ASTM D2986 – DOP. The electrostatic (non-HEPA filtration) filters are tested by Nelson Laboratories for BFE and VFE.

Indications for Use and Environments

Indications for Use –

Anesthesia / Respiratory Filters
For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and / or expired gases is desired.

Model – HEPA filter 3000/04 – Single patient use for exhalation limb of circuit on NPB 700 series ventilators

Models – HEPA filters - 6500/01, 6888/01, 8222/01, 8444/01
Model – Non-HEPA filters - 4000/01
Single patient use up to 24 hours. Patient tidal volumes > 150 ml, when applicable.

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Environment of Use --

Home, Hospital, Sub-acute Institutions, Emergency services

General Technical Characteristics

Attribute	**Air Safety**
Indications for use - To filter inlet, inspired and / or expired gases.	Same
Intended for extended or single patient use up to 24 hours	Yes
Prescription	Yes
Intended population	Any patient some with tidal volumes > 150 ml
Intended Environment of Use	Home, Hospital, sub-acute, Emergency services
Placement in various locations in circuit or ventilator	Yes
Design	
Gas sampling port	Optional
Standard 15/22 mm connectors	Yes
Dead Space (ml)	45 to 84 ml 209 mm for Model 3000/04
Resistance to flow	$\leq$ 3.4 cm H_2O @ 60 Lpm
HEPA – Models – 6500/01, 6888/01, 8222/01, 8444/01 Bacterial filtration – BFE – Nelson	99.99999% Model 3000/04 – 99.9999%
HEPA – Models – 6500/01, 6888/01, 8222/01, 8444/01 Viral filtration – VFE – Nelson	99.99975% Model 3000/04 – 99.9999%
Non- HEPA – Model 4000/01 Bacterial filtration – BFE – Nelson	99.99996%
Non- HEPA – Model 4000/01 Viral filtration – VFE – Nelson	99.99925%
Materials	
Housing polystyrene	Yes
Filter media - HEPA	Paper fiber
Filter Media – Electrostatic – non-HEPA	Polypropylene
Performance Standards	
None under Section 514	Yes
ISO 5356-1 Conical 15/22	Yes
ISO 594-2 Luer Fittings	Yes
DOE 3025-99, DOE 3020-97 and ASTM D2986 - DOP	> 99.97% of 0.3 micron DOP particle @ 60 Lpm

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Differences between Other Legally Marketed Predicate Devices

The data within the submission demonstrates that the proposed devices when compared to the predicate devices are safe and effective and substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 3 2004

Air Safety Ltd.
C/O Mr. Paul Dryden
ProMedic, Inc.
6329 W. Waterview Ct.
McCordsville, IN 46055

Re: K033008
Trade/Device Name: Air Safety HEPA and Non-HEPA Filters
Regulation Number: 21 CFR 868.5620
Regulation Name: Filter, Bacterial, Breathing-Circuit
Regulatory Class: Class II
Product Code: CAH
Dated: March 12, 2004
Received: March 15, 2004

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

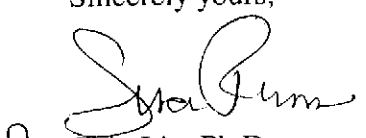
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K033008 (To be assigned)

Device Name: Air Safety HEPA filters
Model 3000/04
Models – 6500/01, 6888/01, 8222/01, 8444/01
Non-HEPA filters – Model – 4000/01

Indications for Use:

Anesthesia / Respiratory Filters
For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and / or expired gases is desired.

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Model – Non-HEPA filters - 4000/01
Single patient use up to 24 hours. Patient tidal volumes > 150 ml, when applicable.

Prescription Use XX **or** **Over-the-counter use __**
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology General Hospital,
Infection Control, Dental Devices

510(k) Number: K033008